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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/863,803	05/22/2001	Jeffrey J. Rade	71699/55591	8907

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EXAMINER	
LI, QIAN J	

ART UNIT	PAPER NUMBER
1632	9

DATE MAILED: 04/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/863,803	RADE ET AL.	
	Examiner	Art Unit	
	Q. Janice Li	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-12 and 14-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-12 and 14-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 May 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

The amendment and response filed 1/23/03 have been entered as Paper No. 8. Claims 2 and 13 have been canceled, and claims 1, 7, and 24 have been amended. Claims 1, 3-12, and 14-28 are pending and under current examination.

Unless otherwise indicated, previous rejections that have been rendered moot in view of the amendment to pending claims will not be reiterated. The arguments in paper #8 would be addressed to the extent that they apply to current rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

WRITTEN DESCRIPTION REQUIREMENT

Claims 1, 3-12, and 14-28 stand rejected, and the rejection has been modified in view of the amendment, under 35 U.S.C. 112, first paragraph, for reasons of record advanced in paper #6 and following.

The amended claims are drawn to using a nucleic acid encoding at least one of the following agents: EPCR, TM, and NF-kB inhibitor (IkB); or *a functional fragment thereof*. In paper #8, Applicants indicated that supports for claiming the "functional fragment thereof" could be found in the specification. These supports will be evaluated one-by-one as follows.

Applicants indicated that the support for EPCR could be found in the last paragraph of page 7 of the specification, and the Summary of the invention. However, the last paragraph of page 7 is under the section of the Summary of the invention, and is the only time EPCR being mentioned in the section. It briefly states EPCR is an example for agents that increase APC, there is no teaching regarding the functional fragments of the EPCR.

Applicants indicated that the support for IkB could be found in page 22 of the specification. However, the discussion of page 22 relies on the disclosure of an abstract by Brockman et al, wherein they teach a particular deletion mutation of NF-kB, there is no teaching regarding the broad scope of "a functional fragment thereof".

Applicants indicated that the support for TM could be found in page 17 of the specification, which relies on U.S. patent 4,912,207, specifically, figure 3 of the cited patent. However, figure 3 of the '207 patent discloses the cDNA sequence of the TM, neither figure 3, nor the text of the specification teaches the structure-functional relationship of the cDNA sequence and the function of the TM fragments, or any consensus region that is crucial to the function of TM, therefore, the teaching of the '207 patent is insufficient to support instant claims.

The Revised Interim Guidelines state "THE CLAIMED INVENTION AS A WHOLE MAY NOT BE ADEQUATELY DESCRIBED IF THE CLAIMS REQUIRE AN ESSENTIAL OR CRITICAL ELEMENT WHICH IS NOT ADEQUATELY DESCRIBED IN THE SPECIFICATION AND WHICH IS NOT CONVENTIONAL IN THE ART" (Column 3, page 71434), "WHEN THERE IS SUBSTANTIAL VARIATION WITHIN THE GENUS, ONE MUST DESCRIBE A SUFFICIENT VARIETY OF SPECIES TO REFLECT THE VARIATION WITHIN THE GENUS", "IN AN UNPREDICTABLE ART, ADEQUATE WRITTEN DESCRIPTION OF A GENUS WHICH EMBRACES

WIDELY VARIANT SPECIES CANNOT BE ACHIEVED BY DISCLOSING ONLY ONE SPECIES WITHIN THE GENUS" (Column 2, page 71436). Considering the breadth of the claims and the number of variations of the agents encompassed by the claims, the disclosure is insufficient to support the broad claims to the genus of functional fragments.

Therefore, for reasons of record and those set forth above, the instant specification fails to meet the written description requirement set forth under 35 U.S.C. §112, 1st paragraph.

ENABLEMENT REQUIREMENT

Claims 1, 3-12, and 14-28 stand rejected, and the rejection has been modified in view of the amendment, under 35 U.S.C. 112, first paragraph, for reasons of record advanced in paper #6 and following.

The claims are drawn to using a functional fragment of EPCR, TM, or I-kB, however, as indicated *supra* in the written description section, the specification fails to provide an adequate description for the broad classes of functional fragments encompassed by the claims. In light of the state of the art, protein chemistry is one of the most unpredictable fields in the biology art. *Bowie et al* (Science 1990 Mar; 247:1306-10) teach that certain positions in the sequence are critical to the three dimensional structure/function relationship and these regions can tolerate only conservative substitutions or none at all (page 1306, column 2). *Rudinger* (Peptide Hormones 1976; June;pages 1-7) teaches the relationship of sequence components and the peptide hormone function, "THE SIGNIFICANCE OF PARTICULAR AMINO ACIDS AND

SEQUENCES FOR DIFFERENT ASPECTS OF BIOLOGICAL ACTIVITY CANNOT BE PREDICTED *A PRIORI* BUT MUST BE DETERMINED FROM CASE TO CASE BY PAINSTAKING EXPERIMENTAL STUDY." (last paragraph of text on page 6). Determination of the effects of particular modifications is not predictable until they are actually made and used, hence resulting in a trial and error situation. Therefore, the general knowledge and levels of skill in the art do not supplement the omitted description, because specific, not general guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the claimed genus, a mutant NF-kB, a cDNA of TM or EPCR alone is insufficient to describe the genus. One cannot extrapolate the teachings of the specification to the scope of the claims because the skilled artisan cannot envision the detailed structures of active agents encompassed by these claims, thus would not know how to use the invention without first carrying out undue experimentation to determine which of the agents would have the recited function. Therefore, in view of the limited guidance, the lack of predictability of the art, and the breadth of the claims, one skill in the art could not practice the invention without undue experimentation as it is broadly claimed.

With regard to the therapeutic aspect of the invention, Applicants argue, in paper #8, that the statement in MPEP 2164.01c could not be used as basis for evaluation because it is drawn to a product claim, whereas applicants claiming a method. Applicant further argue that clinical benefit is not required for enablement, and the present application fully satisfies the "how to make" and "how to use" requirement under 35

U.S.C. §112, 1st paragraph. Applicants go on to argue that Quyang et al and Kim et al references were published well after the priority date of the instant case, so that it is improper to use them as this ground of rejection.

The arguments have been fully considered but they are not persuasive for reasons of record and following.

The statue under 35 U.S.C. 112, first paragraph requires "THE SPECIFICATION SHALL CONTAIN A WRITTEN DESCRIPTION OF THE INVENTION, AND OF THE MANNER AND PROCESS OF MAKING AND USING IT, IN SUCH FULL, CLEAR, CONCISE, AND EXACT TERMS AS TO ENABLE ANY PERSON SKILLED IN THE ART TO WHICH IT PERTAINS, OR WITH WHICH IT IS MOST NEARLY CONNECTED, TO MAKE AND USE THE SAME AND SHALL SET FORTH THE BEST MODE CONTEMPLATED BY THE INVENTOR OF CARRYING OUT HIS INVENTION", which is a requirement for both method and product claims, and which is the basis for the evaluation of claimed invention as cited in the Office action paper #6. The particular citation in MPEP 2164.01c drawn to evaluating a product claim was cited because the claimed methods require that the vascular graft (product) made by the method having the characteristics of "resists failure", which is the goal of the method, and the invention also encompasses a method of transplantation of the transduced graft (e.g. claims 3 and 4), thus, whether the graft resists the failure is one of the very important standard for evaluating whether the method is enabled.

The following is a M.P.E.P. interpretation regarding "how to make" and "how to use" standard. According to MPEP as pursuant to an enabling disclosure required by 35 U.S.C. 112, first paragraph,

"AN APPLICANT'S SPECIFICATION MUST ENABLE A PERSON SKILLED IN THE ART TO MAKE AND USE THE CLAIMED INVENTION WITHOUT UNDUE EXPERIMENTATION.(...) AS SUCH, THE DISCLOSURE MUST TEACH A PERSON SKILLED IN EACH ART HOW TO MAKE AND USE THE RELEVANT ASPECT OF THE

INVENTION WITHOUT *UNDUE* EXPERIMENTATION. FOR EXAMPLE, TO ENABLE A CLAIM TO A PROGRAMMED COMPUTER THAT DETERMINES AND DISPLAYS THE THREE-DIMENSIONAL STRUCTURE OF A CHEMICAL COMPOUND, THE DISCLOSURE MUST

- ENABLE A PERSON SKILLED IN THE ART OF MOLECULAR MODELING TO UNDERSTAND AND PRACTICE THE UNDERLYING MOLECULAR MODELING PROCESSES; AND
- ENABLE A PERSON SKILLED IN THE ART OF COMPUTER PROGRAMMING TO CREATE A PROGRAM THAT DIRECTS A COMPUTER TO CREATE AND DISPLAY THE IMAGE REPRESENTING THE THREE-DIMENSIONAL STRUCTURE OF THE COMPOUND.

IN OTHER WORDS, THE DISCLOSURE CORRESPONDING TO EACH ASPECT OF THE INVENTION MUST BE ENABLING TO A PERSON SKILLED IN EACH RESPECTIVE ART. (MPEP 2106.B.2)

Thus, according to this standard, the vascular graft made by the method must be able to resist graft failure, and the graft encompasses an autologus, allogenic and xenogenic transplant. The specification teaches that using *ex vivo* approach, a replication defective adenoviral vector encoding TM was introduced to rabbit vascular grafts, and the TM was expressed *in vivo* for up to 42 days after implantation, that such procedure reduced bound thrombin activity, and increased the ability for endothelial cells to generate APC (example 5 and fig. 10). The specification speculates that "*protein C is activated to APC thereby inhibiting local thrombin generation. Such local and especially robust inhibition of thrombin generation reduces or eliminated thrombus formation in subject vascular grafts*". (last paragraph in page 6). However, the specification is silent regarding the origin of the graft (autologus?), whether the transduced graft could resist allogenic and xenogenic failure, and whether the increased graft APC has resulted in graft resistance to failure, i.e. whether the goal of the method is resolved. Thus, the specification fails to provide an enabling disclosure commensurate with the scope of the claims. And this is the reason that two post-filing art were cited to illustrate the state of the art, and what is known to the skilled artisan.

With regard to using post-filing art, M.P.E.P. explicitly states, "IF INDIVIDUALS OF SKILL IN THE ART STATE THAT A PARTICULAR INVENTION IS NOT POSSIBLE YEARS AFTER THE FILING DATE, THAT WOULD BE EVIDENCE THAT THE DISCLOSED INVENTION WAS NOT POSSIBLE AT THE TIME OF FILING AND SHOULD BE CONSIDERED. IN *IN RE WRIGHT*, 999 F.2D 1557, 1562, 27 USPQ2D 1510, 1513-14 (FED. CIR. 1993) AN ARTICLE PUBLISHED 5 YEARS AFTER THE FILING DATE OF THE APPLICATION ADEQUATELY SUPPORTED THE EXAMINER'S POSITION THAT THE PHYSIOLOGICAL ACTIVITY OF CERTAIN VIRUSES WAS SUFFICIENTLY UNPREDICTABLE SO THAT A PERSON SKILLED IN THE ART WOULD NOT HAVE BELIEVED THAT THE SUCCESS WITH ONE VIRUS AND ONE ANIMAL COULD BE EXTRAPOLATED SUCCESSFULLY TO ALL VIRUSES WITH ALL LIVING ORGANISMS. CLAIMS NOT DIRECTED TO THE SPECIFIC VIRUS AND THE SPECIFIC ANIMAL WERE HELD NONENABLED". (MPEP 2164.05a) Apparently, it is proper to use a post-filing date art for the purpose of illustrating the levels of the skill in the art.

With regard to the teaching of *Kim et al*, applicants argue, "Kim et al merely points out that increased levels of TM and APC did not seem to result in a reduction in late stage neointimal formation. However, that report does not preclude a beneficial effect on early stage vein graft failure".

The argument has been fully considered but found not persuasive. This is because the claims embrace graft resistance to both the early and late stage failure, not limited to the early stage graft failure, particularly, claims 6, 7, and 12 explicitly recite treating a late stage failure and reduction of neointima. Further, the graft resistance is determined by a serial of biological events that occurred in both the early and late stages, and these events determine the overall graft survival. Thus, only the early stage improvement did not alter the overall graft resistance to failure, as indicated by the

failure in reduction of neointimal formation reported by Kim et al. Additionally, considering the powerful allogenic and xenogenic rejection response, the limited thromboresistance is unlikely to change the outcome of the graft survival.

The newly amended claims recite using EPCR and NF-kB inhibitor, which is supported by prophetic teachings in the specification without any supporting experimental data. This type of teaching does not preclude the enablement of the claims by itself, however, as a novel method and an invention, more is required. M.P.E.P. teaches, "THE TEST OF ENABLEMENT IS WHETHER ONE REASONABLY SKILLED IN THE ART COULD MAKE OR USE THE INVENTION FROM THE DISCLOSURES IN THE PATENT COUPLED WITH INFORMATION KNOWN IN THE ART WITHOUT UNDUE EXPERIMENTATION." (UNITED STATES V. TELECTRONICS, INC., 857 F.2D 778, 785, 8 USPQ2D 1217, 1223 (FED. CIR. 1988)). "DETERMINING ENABLEMENT IS A QUESTION OF LAW BASED ON UNDERLYING FACTUAL FINDINGS". IN RE VAECK, 947 F.2D 488, 495, 20 USPQ2D 1438, 1444 (FED. CIR.1991); ATLAS POWDER CO. V. E.I. DU PONT DE NEMOURS & CO., 750 F.2D 1569, 1576, 224 USPQ 409, 413 (FED. CIR. 1984). One aspect of such factual evidence to be considered is "IF LITTLE IS KNOWN IN THE PRIOR ART ABOUT THE NATURE OF THE INVENTION AND THE ART IS UNPREDICTABLE, THE SPECIFICATION WOULD NEED MORE DETAIL AS TO HOW TO MAKE AND USE THE INVENTION IN ORDER TO BE ENABLING. THE "PREDICTABILITY OR LACK THEREOF" IN THE ART REFERS TO THE ABILITY OF ONE SKILLED IN THE ART TO EXTRAPOLATE THE DISCLOSED OR KNOWN RESULTS TO THE CLAIMED INVENTION. ...ACCORDINGLY, WHAT IS KNOWN IN THE ART PROVIDES EVIDENCE AS TO THE QUESTION OF PREDICTABILITY. IN PARTICULAR, THE COURT IN IN RE MARZOCCHI, 439 F.2D 220, 223-24, 169 USPQ 367, 369-70 (CCPA 1971), STATED: [I]N THE FIELD OF CHEMISTRY GENERALLY, THERE MAY BE TIMES WHEN THE WELL-KNOWN UNPREDICTABILITY OF CHEMICAL REACTIONS WILL ALONE BE ENOUGH TO CREATE A REASONABLE DOUBT AS TO THE ACCURACY OF A PARTICULAR BROAD

STATEMENT PUT FORWARD AS ENABLING SUPPORT FOR A CLAIM. THIS WILL ESPECIALLY BE THE CASE WHERE THE STATEMENT IS, ON ITS FACE, CONTRARY TO GENERALLY ACCEPTED SCIENTIFIC PRINCIPLES. MOST OFTEN, ADDITIONAL FACTORS, SUCH AS THE TEACHINGS IN PERTINENT REFERENCES, WILL BE AVAILABLE TO SUBSTANTIATE ANY DOUBTS THAT THE ASSERTED SCOPE OF OBJECTIVE ENABLEMENT IS IN FACT COMMENSURATE WITH THE SCOPE OF PROTECTION SOUGHT AND TO SUPPORT ANY DEMANDS BASED THEREON FOR PROOF. [FOOTNOTE OMITTED.] (MPEP 2164.02, 03) As a factual finding, it is noted that in the Kim et al reference, it was revealed that the expression of TM was significantly reduced in the untreated vascular grafts, and supplementation of TM leads to an enhanced capacity of grafts to activate protein C at day 7; however, the expression of EPCR was not reduced in the untreated grafts, thus, it is questionable whether supplementation of EPCR could have any effect on graft resistance in light of the findings for TM supplementation. To this end, M.P.E.P. teaches, ""WHEN CONSIDERING THE FACTORS RELATING TO A DETERMINATION OF NON-ENABLEMENT, IF ALL THE OTHER FACTORS POINT TOWARD ENABLEMENT, THEN THE ABSENCE OF WORKING EXAMPLES WILL NOT BY ITSELF RENDER THE INVENTION NON-ENABLED." "LACK OF A WORKING EXAMPLE, HOWEVER, IS A FACTOR TO BE CONSIDERED, ESPECIALLY IN A CASE INVOLVING AN UNPREDICTABLE AND UNDEVELOPED ART." (MPEP 2164.02, 03)

Accordingly, in view of the quantity of experimentation necessary to determine the parameters for obtaining a transduced vascular graft that resists any graft failure (autologus, allogenic, and xenogenic), in particular for using numerous agents and fragments that increase APC, the lack of direction or guidance provided by the specification, and the breadth of the claims directed to a decreased neointima

formation, it would have required undue experimentation for one skilled in the art to practice the claimed invention.

For reasons of record and those set forth above, the instant specification fails to meet the statutory enablement requirement set forth under 35 U.S.C. §112, 1st paragraph.

As indicated in the Office action paper #6, the following art rejections applied even though the Examiner is aware of the contradiction in the sections of enablement rejection and art rejection, and in view of the Office policy for compact prosecution, all issues relevant will put forward in the first action on merits. In paper #8, Applicants have not convincingly addressed the relevant issue, thus, the following rejection maintains.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-6, 8-12, 14-22, and 24-27 stand rejected under 35 U.S.C. 102(e) as being anticipated by *French et al* (US 6,290,949).

In paper #8, Applicants argue that claims as amended feature methods in which at least one of the administered agents is EPCR, hIkB, or a functional fragment thereof, which was not taught by the *French* patent.

In response, the amended claims also read on methods in which at least one of the administered agents is TM, which is fully disclosed by the *French* patent.

Therefore, this rejection stands.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-6, 8-12, 14-23, and 24-28 stand rejected under 35 U.S.C. 103(a) as being unpatentable over *French et al* (US 6,290,949) as applied to claims 1, 3-6, 8-12, 14-22, and 24-27 above, and in view of *Larson et al* (US 6,309,380).

In paper #8, Applicants argue that there is no teaching or suggestion in Larson either alone or together with French that lead on to practice a vascular graft treatment method in which at least one of the administered agents is EPCR, hIkB, or a functional fragment thereof.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208

USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case, the amended claims read on methods in which at least one of the administered agents is TM, which is fully disclosed by the *French* patent. *Larson et al* teach conventional anti-coagulants known in the art, such as coumadin (see paragraph bridging columns 1 & 2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to select one of the conventional anti-coagulant drugs taught by *Larson et al* in the methods taught by *French et al* with a reasonable expectation of success. It would also have been obvious to one of ordinary skill in the art at the time the invention was made to present the recited agents as a kit in a commercial process for the convenience and profit of the commercial activity. Thus, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Therefore, this rejection stands.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 9:00 am - 5:30 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).

Q. Janice Li
Examiner
Art Unit 1632

QJL
April 7, 2003

ANNE M. WEHBE PH.D
PRIMARY EXAMINER